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Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title	:	Certificate of Analysis Finished Product

Product Name	**AZTREOCAN** Injection	**A.R. No.**	BD/FP/23/688
Generic Name	Aztreonam for Injection USP 1000mg	**Sampled qty.**	45 vials
Batch No.	B23675E	**Sampled by**	Arvind
Batch Size	2000 Vials	**Sampled on**	27/01/2024
Mfg. Date	01/2024	**Date of Testing**	27/01/2024
Exp. Date	12/2025	**Date of Release**	11/02/2024

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification	The retention times the major peaks of the sample solution correspond to those of the working standard solution.	Complies
3.	Uniformity of Weight	Average weight ±10%	-0.36% & +0.39%
4.	Average weight	Informative.	1795.3 mg
5.	pH	4.5 to 7.5	6.81
6.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test 1.Particles ≥10 µm 2.Particles ≥25 µm	NMT-6000/vial NMT-600/vial	822/vial 2/vial
	(B.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	Complies
7.	Water	NMT- 2.0% w/w	0.82%w/w
8.	Contents of Arginine	42 to 46%	44.28%
9.	Sterility	No microbial growth should be observed.	Complies
10.	Bacterial Endotoxins	NMT- 0.17 USP EU/mg of Aztreonam.	Less than- 0.17 USP EU/mg of Aztreonam.
11.	Assay: Each glass vial Contains		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Aztreonam (Sterile) USP Eq. to anhydrous Aztreonam (A mixture of Aztreonam & L-Arginine)	1000 mg	974.50 mg	97.45%	90.0% to 105.0%

Remarks: In the opinion of the undersigned the sample referred to above is/~~is not of the standard~~ quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/~~not complies~~ as per ~~IP/~~BP/USP/~~IHS.~~

PACE BIOTECH PAONTA SAHIB (H.P.) Manager 11/02/24

Analysis by	Checked by	Approved by